

**Exhibit 362** [replacing Dkt. #2357-27] attached to Plaintiffs' Consolidated Memorandum in Opposition to Defendants' Motions for Summary Judgment on Plaintiffs' Civil Conspiracy, RICO and OCPA Claims at Dkt. #2182.

- Redactions withdrawn by Defendant

PSJ3  
Exhibit 362

DRAFT with CAH comments/edits**Distributors Securing the Pharmaceutical Supply Chain**

- HDMA is the national association representing primary ~~healthcare pharmaceutical~~ distributors, the vital link between the nation's pharmaceutical manufacturers and healthcare providers. Each business day, HDMA member companies ensure that fifteen million prescription medicines and healthcare products are delivered safely and efficiently to more than 200,000 pharmacies, hospitals, long-term care facilities, clinics and others nationwide.
- HDMA and our distributor member companies are committed to working with all ~~interested parties~~ stakeholders to address the important issue ~~the epidemic~~ of prescription drug diversion and abuse, and ensure the safety of the patient.
- Pharmaceutical distributors play an essential role in helping to maintain the integrity and security of the supply chain and are uniquely positioned to be a key player in the fight against prescription drug abuse.
- HDMA and our distributor member companies support a collaborative approach that is multilayered, approach (such as the one outlined in the ONDCP's 2013 National Drug Control Strategy). This approach including policies would include policies focused in the areas of 1) Education 2) Monitoring 3) Disposal 4) Enforcement. We have a long history of supporting regulations and policies that help ensure the safety, security and efficiency of the pharmaceutical supply chain at both the state and federal levels.
- Initiatives we support include strengthening distributor licensure requirements, establishing and improving Prescription Drug Monitoring Programs (PDMPs), safe drug disposal efforts, legislation addressing gray market issues, and consistent wholesaler reporting requirements that align with federal requirements.

Formatted: Indent: Before: 0.25", No bullets or numbering

Formatted: No bullets or numbering

(Above the line is talking points on the issue of prescription drug abuse and would be used to start all communications. Below the line are talking points addressing Wholesaler Sales Reporting and Wholesaler Thresholds or Limits

- To help prevent against the diversion of controlled substances ensure patient protection at the dispensing level, distributors have controls in place to identify orders that may be prevent prescription drugs from being diverted from their appropriate use, and the controls are
- This includes a regulatory requirement under 21 CFR §1301.74(b), regulated by the Drug Enforcement Agency (DEA). This includes the requirement that distributors operate a system that identifies and reports have a suspicious orders of controlled substances to the Drug Enforcement Administration (DEA) monitoring program.
- Distributors take this responsibility very seriously, and work to help educate their customers regarding DEA's expectations of distributors; distributor's expectations of their

**Comment [GR1]:** We should make this statement more closely track with 21 CFR 1301.74(b) which provides that: "(b) The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency."

pharmacy customers in light of these expectations; and, DEA's expectations of a pharmacist and his or her corresponding responsibility pursuant to 21 CFR §1306.04, do not share specific threshold information with customers as it may potentially give a bad actor the information they need to manipulate the system.

**Comment [GR2]:** Not sure we want to make a sweeping statement on how distributors disclose or do not disclose thresholds. Therefore, we should probably remove this statement that is specific to this point.

- Distributors also support reporting controlled substance data consistent with federal requirements under the Automation of Reports and Consolidated Orders System (ARCOS) data.
- ARCOS is an automated reporting system that tracks Schedule II and some Schedule III narcotic and Gamma-Hydroxybutyric Acid (GHB) narcotic controlled substances from the manufacturer through distribution to the dispensing/retail level.
- According to the DEA, more than 30 million transactions are reported each year by roughly 1,100 distributors and manufacturers; the reports are used by DEA and other federal, state and local investigative agencies to identify the diversion of controlled substances into illicit channels of distribution and the dispensing/retail level."
- ARCOS accumulates these transactions which are then summarized into reports which give investigators in Federal and state government agencies information which can then be used to identify the diversion of controlled substances into illicit channels of distribution".

**Formatted:** Font: (Default) Arial, Complex  
Script Font: Arial

**Formatted:** Font: (Default) Arial, Complex  
Script Font: Arial

**Comment [GR3]:** Revised so it tracks more closely with information/language found on DEA's website concerning ARCOS. See <http://www.deadiversion.usdoj.gov/arcons/index.html>

**Formatted:** Bulleted + Level: 1 + Aligned at: 0.25" + Indent at: 0.5"

**Formatted:** Indent: Before: 0"

- If such ARCOS information would be of value to the States, it would be beneficial for state agencies to request that DEA provide such currently collected distributor data. States would benefit by making inquiries to DEA to determine if the state can have access to data already submitted by distributors for the ARCOS and suspicious orders reporting programs. This would avoid a duplication of efforts by federal and state agencies as well ideally reduce costs and expenses that States would incur in having to individually collect and assess such data, result in substantial savings to the state in potentially significant infrastructure costs while obtaining the data desired.

- If for some reason a State is unable to obtain relevant information directly from DEA, HDMA recommends allowing the reporting of data at the state-level in an identical content and manner that is currently required federally under ARCOS by distributors.
- This will help to ensure consistent reporting and a streamlined and uniform process that can be more readily employed by all parties, government and private, for reports of wholesaler sales of controlled substances that are consistent with DEA requirements.